Complete Summary

GUIDELINE TITLE

Acute rhinosinusitis in adults.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Acute rhinosinusitis in adults. Ann Arbor (MI): University of Michigan Health System; 2005 Feb. 8 p. [6 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. UMHS rhinosinusitis guideline. Ann Arbor (MI): University of Michigan Health System; 1999 Dec. 7 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On June 30, 2006, the Food and Drug Administration notified healthcare professionals and patients that it completed its safety assessment of Ketek (telithromycin), indicated for the treatment of acute exacerbation of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia of mild to moderate severity, including pneumonia caused by resistant strep infections. The drug has been associated with rare cases of serious liver injury and liver failure with four reported deaths and one liver transplant after the administration of the drug. FDA determined that additional warnings are required and the manufacturer is revising the drug labeling to address this safety concern. FDA is advising both patients taking Ketek and their doctors to be on the alert for signs and symptoms of liver problems. Patients experiencing such signs or symptoms should discontinue Ketek and seek medical evaluation, which may include tests for liver function. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acute rhinosinusitis

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Otolaryngology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To improve quality of care and decrease costs by:

- Accurate diagnosis
- Appropriate medical therapy
- Effective radiological imaging
- Appropriate subspecialist referral

TARGET POPULATION

Non-immune compromised adults with suspected or diagnosed acute rhinosinusitis

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Probability estimate via history, physical examination, physician's overall clinical impression, transillumination, and temporality of symptoms
2. Identification of predisposing conditions and complications
3. Diagnostic imaging, including limited sinus computed tomography (CT)

Treatment

1. First line antibiotics: amoxicillin (Amoxil®, Polymox®, Trimox®) or trimethoprim/sulfamethoxazole (Bactrim-DS®, Septra-DS®)
2. Alternative antibiotics for those allergic or intolerant of first line antibiotics, including doxycycline hyclate (Vibramycin®, Doryx®), azithromycin (Zithromax®), cefuroxime axetil (Ceftin®), loracarbef (Lorabid®), clarithromycin (Biaxin®), Clarithromycin XL (Biaxin XL®), Cefprozil (Cefzil®), Cefdinir (Omnicef®)
3. Second line antibiotics: amoxicillin high dose (Amoxil®, Polymox®), amoxicillin/clavulanate potassium, usual dose (Augmentin®), amoxicillin/clavulanate potassium, high dose (Augmentin XR®), levofloxacin (Levaquin®), telithromycin (Ketek®) Note: Guideline developers considered but did not recommend ciprofloxacin (Cipro®) as a second line antibiotic.
4. Adjuvant therapies including:
    - Oral decongestants: pseudoephedrine (Sudafed®)
    - Topical decongestants: oxymetazoline 0.05% (Afrin®)
    - Topical anticholinergics: Ipratropium 0.03 or 0.06% (Atrovent®)
    - Oral antihistamines (first generation with significant anticholinergic effect): chlorpheniramine (Chlor-Trimeton®), clemastine (Tavist®), diphenhydramine (Benadryl®)
    - Corticosteroid nasal spray in high doses: Flunisolide (Nasalide®, Nasarel®) 25 micrograms/spray; fluticasone (Flonase®) 50 micrograms/spray; mometasone furoate (Nasonex®) 50 micrograms/spray
    - Zinc gluconate lozenges
    - Vitamin C
    - Echinacea extract
    - Saline irrigation

    Note: Adjuvant therapy with no proven benefit or not studied in controlling symptoms include steam, saline spray, less-sedating (2nd generation) antihistamines (loratadine, fexofenadine, cetirizine), guaifenesin (except possibly at high doses)

5. Surgery

Management

Referral for otolaryngology evaluation with possible nasal endoscopy and computed tomography

MAJOR OUTCOMES CONSIDERED

- Symptom improvement
- Bacteriologic cure rates
- Efficacy and safety of medications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for this update began with the results of the literature searches performed in 1996 to develop the initial guideline and in 1998 for an update. The literature search conducted in 2004 for this update was conducted prospectively on Medline using the major keywords of acute rhinitis, rhinosinusitis, sinusitis; consensus development conferences, practice guidelines, guidelines, outcomes and process assessment (health care); clinical trials, controlled clinical trials, multicenter studies, randomized controlled trials, cohort studies; adults; English language; and published between 7/1/99 and 4/30/04. Terms used for specific topic searches within major key words included history; physical exam, signs, symptoms, predictors; computed tomography, magnetic resonance imaging, x-ray, ultrasound; sinus aspiration; nasal culture; diagnosis not included above; observation, saline, steam, postural drainage, salt water gargle; decongestants; cough suppressants; antihistamines, antibiotics; guaifenesin; corticosteroids; zinc, vitamin C; ipratropium; capsaicin, Echinacea, treatment failure, recurrence, persistent; immunocompromised, immunosuppressed, transplant; treatment or management not included above. Specific search strategy available upon request.

The search was conducted in components each keyed to a specific causal link in a formal problem structure. The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence for the most significant recommendations:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

When possible, conclusions were based on prospective randomized clinical trials. In the absence of randomized controlled trials, observational studies were considered. If none were available, expert opinion was used.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A limited sinus computed tomography (CT) ($644) provides adequate information compared to a full sinus CT scan/maxillofacial CT ($1,193) and provides much better definition than a plain sinus x-ray series ($279).

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

University of Michigan Health System (UMHS) guidelines are reviewed by leadership and in clinical conferences of departments to which the content is most relevant. Guidelines are then endorsed by the Executive Committee for Clinical Affairs.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on best predictors of rhinosinusitis, preferred treatment regimens, and dosing and cost considerations for first and second trial antibiotic treatments.

The levels of evidence [A-D] are defined at the end of the "Major Recommendations" field.

Definitions

Acute rhinosinusitis is an inflammation of the paranasal sinuses and the nasal cavity lasting no longer than 4 weeks. It can range from acute viral rhinitis (the common cold) to acute bacterial rhinosinusitis. Fewer than 5 in 1,000 colds are followed by bacterial rhinosinusitis.

Diagnosis

Estimate the probability of acute bacterial rhinosinusitis based on history and physical examination. The best predictors include maxillary toothache, poor response to decongestants, patient report of colored nasal discharge, purulent secretions by exam, and abnormal transillumination.

Treatment

Prescribe antibiotic therapy based on benefits and risks. Benefits depend on the probability of bacterial infection and the severity of symptoms. Risks of antibiotics include allergic reaction, potential side effects, and promotion of bacterial resistance. Antibiotics have not been shown to decrease the risk of complication or progression to chronic rhinosinusitis. Symptoms resolve within two weeks without antibiotics in 70% of cases and with antibiotics in 85% of cases.

First line antibiotics for acute bacterial rhinosinusitis are amoxicillin and trimethoprim/sulfamethoxazole. They are superior to placebo and as effective as other agents that are more expensive, have greater risk of side effects, and/or should be reserved for more serious infections [A]. Use first-line alternatives (e.g., doxycycline, azithromycin) only for patients allergic to both first line drugs. The usual initial course of antibiotics should be 10 to 14 days. An exception is azithromycin (500 mg daily), which should be prescribed for 3 days.

For partial but incomplete resolution after an initial course of antibiotics, extend the duration of antibiotic therapy by an additional 7 to 10 days for a total of 3 weeks of antibiotics.

For minimal or no improvement with initial treatment, consider changing to an antibiotic with broader coverage, including resistant strains. Options include amoxicillin at high dose, amoxicillin/clavulanate, and levofloxacin. Avoid ciprofloxacin due to limited activity against Streptococcus pneumoniae.

Ancillary therapies for acute rhinosinusitis have little supporting data. Some studies examining treatments for viral upper respiratory infections have shown:

- Efficacy in symptom control: decongestants and anticholinergics, including "first-generation" antihistamines (diphenhydramine, chlorpheniramine, clemastine) [A].
- Possible efficacy: zinc gluconate lozenges, vitamin C, Echinacea extract, saline irrigation [conflicting or insufficient data].
- No significant benefit: guaifenesin (except possibly at high dose), saline spray, steam, "non-sedating" antihistamines (loratadine, fexofenadine, cetirizine).

For recurrent acute rhinosinusitis or acute rhinosinusitis superimposed on chronic rhinosinusitis, the addition of high dose nasal corticosteroids may decrease duration of symptoms and improve rate of clinical success [A]. However, this approach is inconvenient, has potential side effects, and significant cost.

Imaging

If symptoms of rhinosinusitis persist for more than three weeks despite antibiotics or recur more than three times per year, a limited sinus computed tomography (CT) scan (coronal plane) should be performed while the patient is symptomatic to reassess diagnosis and determine need for referral [C, D]. A limited sinus CT ($644) provides adequate information compared to a full sinus CT scan/maxillofacial CT ($1,193) and provides much better definition than a plain sinus x-ray series ($279). Plain sinus x-rays, therefore, are not recommended.

Definitions:

Levels of evidence for the most significant recommendations:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the diagnosis of acute bacterial rhinosinusitis.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for the most significant recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis and appropriate treatment of acute rhinosinusitis

POTENTIAL HARMS

- Risks of treating with antibiotics include severe allergic reaction, potential antibiotic side effects, and bacterial resistance.
- Topical decongestant agents should not be used more than 3 days because of risk of rebound vasodilation (rhinitis medicamentosa) or atrophic rhinitis.
- Although they have not been found to affect blood pressure significantly in patients with stable hypertension, oral decongestants should be used with caution in patients with hypertension, ischemic heart disease, glaucoma, prostatic hypertrophy, or diabetes mellitus.
- Geriatric patients may be more sensitive to the effects of oral decongestants.
- Note that antihistamines may impair psychomotor performance often without sedation or other noticeable symptoms. Patients should not drive or operate heavy machinery while using them. Also, avoid use in elderly patients (> 65-70 years of age) due to risk of delirium and cognitive decline.
- Steroids could have significant side effects

CONTRAINDICATIONS

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Oral decongestants are contraindicated in patients using monoamine oxidase inhibitors (MAOIs) or having uncontrolled hypertension or severe coronary artery disease.

QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Acute rhinosinusitis in adults. Ann Arbor (MI): University of Michigan Health System; 2005 Feb. 8 p. [6 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 May (revised 2005 Feb)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Rhinosinusitis Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Leader: Jane T. McCort, MD, General Internal Medicine

Team Members: R. Van Harrison, PhD, Medical Education; James F. Peggs, MD, Family Medicine; Jeffrey E. Terrell, MD, Otolaryngology

Guidelines Oversight Team: Connie J. Standiford, MD; Lee A. Green, MD, MPH; R. Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Member; Company; Relationship

Jane T. McCort, MD (none)

R. Van Harrison, PhD (none)

James F. Peggs, MD (none)

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following is available:

- Sinusitis (acute bacterial rhinosinusitis). University of Michigan Health System; 2005 Jan. Various p. Electronic copies: Available from the University of Michigan Health System Web site.
- Viral prescription pad - no antibiotics. Centers for Disease Control and Prevention. 1 p. Electronic copies: Available from the Centers for Disease Control and Prevention Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000. This NGC summary was updated on May 16, 2005. The updated information was verified by the guideline developer on May 20, 2005. This summary was updated by ECRI on January 27, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Ketek (telithromycin). This summary was updated by ECRI on July 3, 2006 following the updated U.S. Food and Drug Administration (FDA) advisory on Ketek (telithromycin).

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DISCLAIMER

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Date Modified: 9/25/2006